Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Applicants would like to note that given the refusal to interview this case before the shortened three-month deadline of September 29, 2007, Examiner Boesen and the undersigned attorney have set up a telephone interview to take place after submission of this response. Examiner Boesen agreed that applicants would be permitted to file a supplemental response, if necessary, following the telephone interview.

Claims 1, 14, 15, and 31 have been amended, and claims 5, 6, 9-12, 50, 53, and 54 have been cancelled without prejudice. Claim 1 has been amended to recite that the functional group comprises a primary amine or trimethylaminoethyl ("TMAE") group. Descriptive support for these limitations appears in original claims 5, 10, and 11. Claims 14 and 15 have been amended to present better images of the structures introduced in applicants' prior response.

New claims 55 and 56 have been introduced. Descriptive support for the subject matter of claims 55 and 56 appears at page 14, third paragraph, and the amended paragraphs (discussed below). No new matter has been introduced.

Claims 1, 2, 13-33, 51, 52, 55, and 56 are pending.

The specification has been amended to reflect the structure of several of the polymer matrices, including FRACTOGEL™ EMD, TOYOPEARL™, and TSK-GEL™. Because the structures of these materials were known to persons of skill in the art prior to the filing date of the present invention, for reasons discussed in the prior response submitted on April 30, 2007, entry of the structures that correspond to these tradename materials does *not* constitute new matter.

The rejection of claims 14 and 15 under 35 U.S.C. § 112 (first paragraph) for lack of written descriptive support is respectfully traversed in view of the accompanying amendments to the specification. The U.S. Patent and Trademark Office ("PTO") has asserted that the structures appearing in claims 14 and 15 must also be presented in the specification. Because the structures can be entered into the specification without introduction of new matter (and applicants have amended the specification to recite these same structures), the rejection of claims 14 and 15 is improper and should be withdrawn.

The rejection of claims 1, 2, 5, 8, 9-33, and 50-54 under 35 U.S.C. § 112 (first paragraph) for lack of enablement is respectfully traversed in view of the above amendments. Claim 1 presently recites that the "...the prion protein binding material comprises a polymer matrix attached to a functional group, which functional group comprises a primary amine or trimethylaminoethyl group...." Applicants respectfully submit that the results presented in Tables 1 and 3 fully support the use of polymer matrixes comprising these two types of functional groups (*see* Table 1, lines 11 and 44). Because the specification fully supports use of the recited binding materials, the rejection of claims 1, 2, 5, 6, 9-33, and 50-54 for lack of enablement is improper and should be withdrawn.

The rejection of claims 1, 2, 5, 6, 9-33, 50-52, and 54 under 35 U.S.C. § 102(b) as anticipated by Foster et al., *Vox Sanguinis* 78:86-95 (2000) ("Foster") as evidenced by the Affinity Chromatography data sheet, Cat #28 A21DS ("Affinity data sheet") is respectfully traversed.

Foster discloses a method for manufacturing plasma proteins using various steps of precipitation as well as a DEAE Toyopearl™ 650 M ion exchange resin during factor VIII preparation. The DEAE functional group is neither a primary amine nor TMAE. Because claim 1 does not read on the resin employed by Foster, the rejection of claims 1, 2, 5, 6, 9-33, 50-52, and 54 as anticipated by Foster is improper and should be withdrawn.

Moreover, given the data of record demonstrating the specific and selective prion protein-binding behavior of claimed binding materials—that possess either a primary amine functional group or a TMAE functional group—as compared to the non-specific binding behavior of the Foster material that contains a DEAE functional group, applicants submit that the presently claimed invention would not have been obvious over Foster.

The rejection of claims 1, 2, 5, 6, 9-33, 53, and 54 under 35 U.S.C. § 103(a) for obviousness over U.S. Patent No. 6,221,614 to Prusiner et al. ("Prusiner") in view of Kragten et al., *J. Biol. Chem.* 273:5821-5828 (1998) ("Kragten") and the Affinity data sheet is respectfully traversed.

Prusiner teaches the use of a polymer coated with a prion complexing agent, which is used in chromatography to physically separate the prion bound to the complexing agent from a solution such as blood or plasma. The complexing agent, such as an antibody or phosphotungstic acid ("PTA") or trichloroacetic acid ("TCA"), or a combination thereof, is immobilized on the chromatography bead or resin.

Kragten teaches a putative mechanism of action for the drug R-Deprenyl, which is used for the treatment of Parkison's disease. Kragten specifically reports the detection of an interaction between R-Deprenyl and the related compound CGP-3466 with glyceraldehyde-3-phosphate dehydrogenase. This was accomplished using affinity chromatography that employed R-Deprenyl or CGP-3466 immobilized on Toyopearl™ AF 650M.

The Affinity data sheet is relied upon merely for the known use of Toyopearl™ AF 650M as a substrate used for protein purification.

Applicants submit that the rejection is improper for several reasons.

Firstly, applicants submit that the person of ordinary skill in the art would not have been motivated to combine the teachings of Prusiner and Kragten, because Kragten represent non-analogous art for the reasons identified in applicants response filed on April 30, 2007 (*see* page 14 of prior response).

Secondly, even if the person of ordinary skill in the art would have combined the teachings of Prusiner and Kragten, the combination of these references (with or without the Affinity Data Sheet) fails to teach each and every limitation of the claimed invention. In particular, the combination of these references fails to teach or suggest a "binding material [that] comprises a polymer matrix attached to a functional group, which functional group comprises a primary amine or trimethylaminoethyl group…" as now required by amended claim 1.

Quite the contrary, both Prusiner and Kragten teach the modification of the resin functional groups. Prusiner modifies resin or membrane material with its complexing agent—e.g., an antibody, PTA, TCA, etc. As described in Example 2 of Prusiner, the amine substituted nylon membrane is bound with IgG, thereby destroying the primary amine groups thereon. In much the same way, Kragten modifies the Toyopearl™ AF Amino 650 resin with CGP3466 or demethyldeprenyl, which is illustrated in Figures 1D,E thereof. In both cases, the primary amine group of the starting material is functionalized with another component *prior* to use of the materials.

Thus, neither reference, let alone the combination thereof, teaches a method of forming a complex between a prion protein and a prion protein binding material in a sample where "the prion protein binding material comprises a polymer matrix attached to a functional group, which functional group comprises a primary amine or trimethylaminoethyl group, and wherein the binding material binds specifically and selectively to the prion protein." The Affinity data sheet provides no suggestion to the skilled artisan that

Toyopearl™ AF Amino 650 resin, without modification, is capable of use in the claimed method, particularly given the teaching away by Prusiner and Kragten.

For these reasons, the rejection of claims 1, 2, 5, 6, 9-33, 53, and 54 for obviousness over Prusiner in view of Kragten and the Affinity data sheet should be withdrawn.

The provisional obviousness-type double patenting rejection of claims 1, 2, 5, 6, and 8-33 over claims 1-20 of co-pending U.S. Patent Application Serial No. 10/962,670 should be withdrawn. As a provisional rejection, which is the only remaining rejection (i.e., all of the rejections set forth above should be withdrawn in view of the accompanying amendments and remarks), it is appropriate for the PTO to withdraw this rejection in a manner consistent with MPEP § 804.I.B.1 (*see* page 800-17).

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: September 18, 2007

/Edwin V. Merkel/
Edwin V. Merkel
Registration No. 40,087

NIXON PEABODY LLP
Clinton Square, P.O. Box 31051
Rochester, New York 14603-1051
Telephone: (585) 263-1128
Facsimile: (585) 263-1600